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EXAMINER
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TON, THAIAN N

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 12/24/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/913,854

Applicant(s)

ANDREWS ET AL.

Examiner

Thai-An N Ton

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 19-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 25 is/are rejected.
- 7) ☒ Claim(s) 4,6,10,12 and 18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

The prior Office action, mailed 8/13/03, is withdrawn. A new time period for response has been restarted with the mailing of this Office action.

In a telephonic conversation with Barbara McDowell, on November 4, 2003, it was brought to the Examiner's attention that the claims examined in the prior Office action, mailed 8/13/03, Paper No. 9, did not include claims that were amended under Article 19. The instant Office action includes the amendments to the claims under Article 19.

Claims 1-25 are pending. Claims 1-18 and 25 are under current examination. Claims 19-24 are withdrawn from consideration.

### *Election/Restrictions*

Claims 1-18 and 25 are found to correspond to the claims recited in Group I of the Restriction requirement mailed on 5/7/03, Paper No. 7. Applicants elected Group I with traverse in Paper No. 8. The traversal was not found to be persuasive in the Office action mailed 8/13/03, see p. 2. Accordingly, claims 19-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected groups, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

*Claim Objections*

Claim 12 is objected to as being a substantial duplicate of claim 10. Claim 4 is objected to as being a substantial duplicate of claim 6.

Claim 18 is objected to because the term "least" is misspelled.

Appropriate correction is required.

*Claim Rejections - 35 USC § 101*

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are directed to a diploid cell which possesses at least one pluripotential characteristic, which includes the ability to differentiate into at least one selected tissue type, and the cell comprises at least part of the cytoplasm derived from a mammalian embryonal stem cell or embryonal germ cell combined with a nucleus of a somatic cell. This is non-statutory because the claimed cells encompass any somatic cell that can differentiate into a selected tissue type, for example, hematopoietic stem cells, found in an individual. As all cells are originally "derived" from an embryonic stem cell, the cytoplasm of any cell would be derived from an embryonic stem cell. The recitation of the term "isolated" would obviate this rejection.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for preparing a cell that expresses Oct4 comprising 1) combining at least one embryonal stem or embryonal germ cells with at least one somatic cell; 2) removing from the combined cell the embryonal stem or embryonal germ nucleus, 3) culturing the cell under conditions conducive to proliferation and expansion of said cell, and 4) optionally storing said cell culture under suitable storage conditions and methods for preparing a cell that expresses Oct4, comprising 1) providing at least one embryonal stem or embryonal germ cell, 2) separating at least part of the cytoplasm from the nucleus of said embryonal stem or embryonal germ cell; 3) isolating the cytoplasmic part, 4) combining the cytoplasmic part with at least one somatic cell, 5) growing the combined cell in culture and 6) optionally storing the combined cell under suitable storage conditions, does not reasonably provide enablement for cells that possess at least one pluripotential characteristic, which includes the ability to differentiate into at least one selected tissue type, and methods of making such cells. The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to diploid cells which possess at least one pluripotential characteristic, which includes the ability to differentiate into at least one selected tissue type, wherein the cell comprises at least part of the cytoplasm derived from a mammalian embryonal stem cell or embryonal germ cell combined with a nucleus of a somatic cell, and in further embodiments, the pluripotential marker is the expression of Oct4. In further embodiments, the claimed invention is directed to methods for preparing a cell by nuclear transfer comprising combining at least one embryonal stem/embryonal germ cell with at least one somatic cell, removing the embryonal/embryonal germ cell nucleus from the combined cell, culturing the cell under conditions under conditions conducive to proliferation and expansion of said cell, and optionally storing said combined cell under suitable conditions. In further embodiments, the claims are directed to methods of preparing a cell by nuclear transfer by isolation of a cytoplasmic part of an embryonal stem/embryonal germ cell and combining the cytoplasmic part with at least one somatic cell, growing the combined cell in culture and optionally storing the combined cell under suitable storage conditions.

The specification teaches the generation of cytoplasts, derived from ES/EG cells, which are fused with selected somatic cells to form cybrids in order to reprogram the differentiated somatic cell nucleus. This cybrid can then be

proliferated to establish pluripotent cell lines. See pp. 6-7, bridging ¶. In particular, the specification teaches that the pluripotent cells express genes, such as Oct4, that are not typically expressed by differentiated cells, and that expression of such genes would provide evidence as to whether a somatic cell nucleus has been reprogrammed. See p. 8, lines 25-28. In particular, the specification teaches the fusion of human EC cells with mouse thymocytes using polyethylene glycol. See pp. 15-16. The resulting heterokaryons were plated and incubated for 2 days, wherein the non-attached cells were aspirated and the remaining cells harvested. The cells were then analyzed for the expression of Oct-4 by PCR. The specification teaches the enucleation of the ES/EG cells to yield cytoplasm donors [karyoplasts] [see pp. 17-18], methods for fusing the cytoplasm of one cell with the nucleus of another [pp. 18-19] and the various somatic cells that may be used as nuclear donors [p. 20]. The specification teaches that that in order to test the ability of a human EC cell cytoplasm to reprogram somatic cells, isolated mouse thymocytes were fused with human 2102Ep EC cells to produce heterokaryons which were tested after 2 days, for the activation of Oct4 from the thymocyte genome. See p. 28, lines 9-24. The specification teaches that human Oct4 expression was detected in the thymocyte fused cells, as well as in the mock fusion experiment, which is consistent with the human Oct4 expression in the human EC cells. It was found that mouse Oct4 was detected in only the human-mouse fused cells. See p. 29. The specification further teaches that in a second experiment, where human 2102Ep and TERA1 EC cells

were fused with mouse thymocytes, mouse Oct4 was detected in the fusion of the 2102Ep cells, suggesting that the TERA1 cytoplasm did not achieve reprogramming. See p. 29, lines 10-17.

The specification fails to provide teachings or guidance with regard to the claimed invention to show that the cells produced by the claimed method are pluripotent, as required by the claims. Note that the product claims (claims 1-12, 18 and 25) have been included in this rejection because they encompass pluripotent cells made by the claimed method. The specification clearly teaches that the claimed methods would be used to produce pluripotent cells. See p. 7, lines 17-18, for example. However, the only teachings provided by the specification show that the expression of mouse Oct4 in the experiments involving the fusion of the human EC cell line, 2102Ep and mouse thymocytes indicates that the mouse thymocytes were reprogrammed. However, the specification teaches another human EC cell line, TERA1, was unable to reprogram the mouse thymocytes, as shown by the lack of expression of mouse Oct4. As such, the specification teaches only one example to show reprogramming in mouse thymocytes, as evidenced by the expression of Oct4. However, it is known in the art that the expression of Oct4 is not necessarily an indicator of pluripotency. For example, Monk and Holding [*Oncogene*, 20:8085-8091 (2001)] found that Oct4 is expressed in human tumors. See *Abstract*. Monk & Holding compare the expression of embryo-specific genes in tumor and normal tissues [see Figure 3] and found that the known embryonic gene, Oct4, was



expressed in the panel of tumors, and at high levels in blastocyst and cancer cells, but at much lower levels in normal tissue. See Figure 5. As such, the art supports that although Oct4 is recognized as an embryonic gene, the mere detection of expression of Oct4 is not an indicator of pluripotency, because tumor tissues, as well as normal tissues, express Oct4.

The specification further teaches that primate ES cells exhibit a range of characteristics or markers that are associated with pluripotency. For example, specific cell surface markers [SSEA-3 (+), SSEA-4 (+), TRA-1-60 (+), TRA-1-81 (+)], have stable karyotypes, continue to proliferate in culture in an undifferentiated state, and have the ability to differentiate into all three embryonic germ layers [see p. 3, lines 16-23]. Furthermore, the specification teaches that primate ES cell lines show high levels of telomerase activity [see p. 3, lines 25-29], and that a pluripotential characteristic is a chromosomal methylation pattern characteristic of pluripotential cells [p. 9-10, bridging ¶], and that the cells when introduced into an animal, have the ability to induce tumors into the animal [p. 10, lines 11-13].

However, the specification fails to provide specific teachings or guidance to show that the methods of the claimed invention would, indeed, produce cells that are pluripotent. The specification's showing of Oct4 expression in the fused heterokaryons is not enabling, as shown *supra*, that the mere expression of Oct4 is not necessarily indicative of pluripotency. The specification fails to teach that the cells of the claimed invention express specific cell surface markers that are

indicative of pluripotent cells, that the cells of the invention show high levels of telomerase activity, are methylated in a pattern characteristic of pluripotent cells, or are able to induce tumors when introduced in an animal, as required by the claims. As such, the specification fails to provide an enabling disclosure for the generation and use of the claimed cells.

It is noted that certain of the instant claims are directed to methods which generate a nuclear transfer unit, wherein the NT unit is further cultured under conditions to proliferate the NT unit. See part (iii) of claim 13, for example. However, it is well-known in the nuclear transfer art that activation of the resulting nuclear transfer unit must take place in order to effect further development. However, the claims do not provide such steps. Dinnyés *et al.* [Cloning & Stem Cells, 4 :81-92 (2002)] report on the state of the art of somatic cell nuclear transfer, stating that, "NT is a complex procedure and each step effects the overall efficiency. The unpredictability of the technology due to biological variation of the recipient oocytes and the donor cells is difficult to control. Therefore, standardization of the steps is important in order to obtain consistent results." See p. 83, 1<sup>st</sup> column, 2<sup>nd</sup> full ¶. With particular regard to the importance of activation of oocytes, Dinnyés state that, "In NT, the lack of sperm-induced fertilization steps necessitate the application of an artificial activation in order to trigger further development." See p. 83, 2<sup>nd</sup> column, last ¶.

Furthermore, with regard to claim 5, which is directed to a diploid cell which possesses at least one pluripotent characteristic, which is the ability to differentiate into at least one selected tissue type, wherein the cell comprises at least part of the cytoplasm derived from a mammalian embryonal stem cell or mammalian germ cell combined with a nucleus of a mammalian somatic cell, wherein the cell expresses Oct4. The claim, as written, describes a nuclear transfer unit wherein the NT unit expresses Oct4. The specification fails to provide teachings or guidance to show that a NT unit as claimed would express Oct4. For example, the specification teaches that the heterokaryon fusion of human EC cells and mouse thymocytes where the cells were first fused, plated and then incubated for 2 days. After 2 days, the non-attached cells were aspirated and the remaining cells analyzed by PCR for the expression of Oct-4. See pp. 15-16. The specification teaches that the expression of Oct-4 indicates the reprogramming of a somatic cell nucleus to an ES/EC cell like state [see p. 28, lines 16-19]. The specification teaches that, "Following fusion to combine a differentiated cell and an ES/EG cell, with prior or subsequent removal of the ES/EG cell nucleus, it is necessary to provide appropriate conditions for the re-programming of the differentiated cell nucleus and the subsequent proliferation of the resulting RPES [Reprogrammed Embryonic Stem] cells." See p. 24, lines 15-18. As such, the specification provides support for cells which are cultured from the NT unit that subsequently express Oct-4, however, the specification fails to provide sufficient teachings or guidance to show that the NT

unit itself would express Oct-4, as the specification clearly shows that the growth and proliferation of the original NT unit for 2 days prior to analysis for Oct-4 expression.

Accordingly, in view of the lack of specific teaching or guidance provided by the specification with regard to the pluripotency of the cells produced by the nuclear transfer methods, other than the mere expression of Oct4, the state of the art, which teaches that Oct4 is expressed in normal, cancerous and embryonic tissues, the requirement for activation of the nuclear transfer unit to produce a successful nuclear transfer, it would have required undue experimentation for one skilled in the art to make and use the claimed invention.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, as written, is unclear as it reads on a cell *in vitro* and *in vivo*. Thus, it is unclear if the claim is directed to an isolated cell, or a cell inside of an animal? Claims 2-18 and 25 depend from claim 1.

Claims 2-10, 12-17 and 25, as written, are unclear. The claims refer to "a cell according to claim 1" (or a claim dependent upon claim 1). Claim 1 refers to a particular cell. The recitation of "the cell according to claim 1" would overcome this rejection.

Claim 3 recites that the cell, "has the capacity" to proliferate in continuous culture. This phrase is unclear because it is unclear whether these characteristics actually occur or that the cells could potentially do these described things. "The capacity" implies a latent property and the conditions for the latent property must be clearly defined. Therefore, it is unclear if the latent property is ever obtained.

Claim 9, as written, is vague. The claim recites that the cell, "includes the presence of a chromosomal methylation pattern characteristic of pluripotential cells". This is unclear because it would not be expected that all types of pluripotent cells would express the same methylation pattern. For example, would adult pluripotent stem cells have the same methylation pattern as other pluripotent stem cells? Clarification and/or amendment to the claim is requested.

Claims 13-15 recite the term "/" (e.g., embryonal stem/embryonal germ). This renders the claims vague and indefinite because the term "/" is intended to further limit or expand the claim. Claim 17 depends from claim 13; claim 16 depends from claim 15.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-12, 18 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* [Nature, 292:154-156 (1981)].

The claims are directed to a cell comprising at least part of the cytoplasm derived from an embryonal stem cell or embryonal germ cell combined with a nucleus of a somatic cell. In further embodiments, the cell has pluripotential characteristics that includes the expression of at least one selected marker of pluripotential cells, the cell can proliferate in continuous culture in an undifferentiated state for at least six months, and can induce tumors when introduced into an animal.

Note that the claims recite that the cytoplasm is "derived from" an embryonal stem cell or embryonal germ cell, and that this language encompasses cytoplasm from any cell, because all cells are derived from embryonal stem cells.

Evans teach the generation of pluripotent cell lines which are isolated from mouse blastocysts. The cell lines have normal karyotypes, can be maintained for over 30 passages *in vitro*, and when injected into mice, produced tumors. See p. 255, 1<sup>st</sup> column, ¶s 1-2. The cells as taught by Evans anticipate the claimed invention because the cytoplasm from these cells are derived from an embryonal stem cell.

Note further that claim 25 is directed to a kit comprising the cells of claim 1, instructions with respect to maintenance of the cell in culture, and optionally

factors required to induce differentiation of the cell into at least one desired tissue type or organ.

*In re* Gulack (CAFC) 217 USPQ 401 relates to a measuring cup. In the case of *In re* Gulack, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself, which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed kit. The components of the kit remain fully functional absent the printed instructions for use. Thus, the instructions for use included in a kit or article of manufacture constitute "intended use" for that kit or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03:

Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. *In re* Casey 370 F.2d 576, 152 USPQ 235 (CCPA 1967); *In re* Otto, 312 F.2d 937, 938, 136 USPQ 458, 459, (CCPA 1963).

In the instant case, the claim is drawn to a kit comprising the cells of claim 1, instructions with respect to maintenance of the cell in culture, and optionally factors required to induce differentiation of the cell into at least one desired tissue type or organ. The intended use which is recited on the instructions lacks a functional relationship to the kit because the instructions do not physically or

chemically affect the chemical nature of the components of the kit, and furthermore, the components of the kit can still be used by the skilled artisan for other purposes (as a whole or individually). Therefore, the kit is unpatentable over the prior art because they function equally effectively with or without the instructions, and accordingly no functional relationship exists between the instructions for use and the kit components.

Accordingly, Evans anticipates the claimed invention.

Claims 1-12, 18 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomson [WO 96/22362, published 25 July 1996].

The claims are directed to a cell comprising at least part of the cytoplasm derived from an embryonal stem cell or embryonal germ cell combined with a nucleus of a somatic cell. In further embodiments, the cell has pluripotential characteristics that includes the expression of at least one selected marker of pluripotential cells, the cell can proliferate in continuous culture in an undifferentiated state for at least six months, the cell has the pluripotential characteristic that includes the presence of telomerase activity, and a chromosome methylation pattern characteristic of pluripotential cells, and can induce tumors when introduced into an animal.

Thomson teach the isolation and purification of primate embryonic stem cells that are capable of indefinite proliferation *in vitro* in an undifferentiated state, are



capable of differentiation to derivatives of all three embryonic germ layers, and maintain a normal karyotype throughout prolonged culture. The pluripotent cells are negative for SSEA-1, positive for the SSEA-3 marker, positive for the SSEA-4 marker, TRA-1-60, TRA-1-81 and alkaline phosphatase. Thomson teach that the primate cells can continue to proliferate in an undifferentiated state for at least one year. See p. 7, lines 9-32. Thomson teach that tumors formed after injection of rhesus ES cells into the hindleg muscles of SCID mice [see Figure 5].

Note that, as discussed above, the claim 25, which is directed to a kit, comprising the cells of the claimed invention, wherein the intended use of the kit is recited on the instructions, the intended use of the kit does not impart patentable weight.

Accordingly, Thomson anticipates the claimed invention.

Claims 1-12, 18 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell *et al.* [WO 97/07668, published 6 March 1997] as evidenced by Thomson [WO 96/22362, published 25 July 1996] and Pesce *et al.* [Stem Cells, 19:271-278 (2001)].

Campbell teaches the reconstruction of mammalian embryos by nuclear transfer, in particular, the transfer of a donor nucleus into an enucleated oocyte. Note that the enucleated oocyte, as taught by Campbell, fulfills the limitations of the claims in that the oocyte has at least part of its cytoplasm derived from an ES

cell or EG cell, because the oocyte is derived from an ES cell. Campbell teach that the nuclear donor can be any type of cell: fully or partially differentiated or undifferentiated cells. See p. 8, lines 13-27. Campbell teach that the mammalian embryos produced by nuclear transfer can then be developed to produce a full term animal. See p. 15, lines 19-29. In particular, Campbell teach the reconstruction of bovine embryos by nuclear transfer [see pp. 25-26], and the production of ovine embryos by nuclear transfer [see pp. 26-28]. Campbell teach that the reconstructed ovine embryos were transferred in a recipient ewe and a live lamb was born. See p. 28 and Table 5. Because Campbell teaches the generation of a live animal from a nuclear transfer unit, Campbell clearly teaches that the nuclear transfer unit can differentiate into at least one selected tissue type [claim 3] and that it is pluripotent.

Note that some of the instant claims are directed to properties that are inherent to pluripotent cells. For example, that the cell expresses a selected marker of pluripotential cells, which is Oct4 [claim 5], that the cell includes the presence of telomerase activity [claim 8], that the cell includes the presence of a chromosomal methylation pattern [claim 9], that the cell can induce tumors when introduced into an animal [claims 10 and 12].

“Products of identical chemical composition can not have mutually exclusive properties.” A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Thomson provides evidence that pluripotent cells form tumors after injection of rhesus ES cells into the hindleg muscles of SCID mice [see Figure 5], and that the cells are capable of differentiation into all tissues derived from all three embryonic germ layers [see Abstract]. Pesce provides evidence to show that pluripotent cells express Oct-4. For example, they teach that "Oct-4 transcription factor is expressed in mouse totipotent embryonic stem and germ cells." See *Abstract*. They further teach that Oct-4 ortholog genes are highly conserved and have been identified in other mammalian species. See p. 272, 1<sup>st</sup> col., 2<sup>nd</sup> ¶. Accordingly, the various properties recited by the claims would be inherent to pluripotent stem cells.

Note that, as stated *supra*, claim 25 which is directed to a kit comprising the cells wherein the intended use of the kit is recited on the instructions, the intended use of the kit does not impart patentable weight.

Accordingly, Campbell anticipate the claimed invention.

Art Unit: 1632

*Conclusion*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Note: After January 13, 2004, the Examiner may be reached at (571) 272-0736. If the Examiner is unavailable, inquiries may be directed to Deborah Reynolds, SPE of Art Unit 1632, at (571) 272-0734.

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